Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)
Approved for use through xx/xx/200x. OMB 0651-00xx
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional) 2119-4281US1	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]	Application Number 10/600,230 / Filed June 20, 2003
	First Named Inventor Wilkinson
on March 22, 2007	
Signature /Janet Cotto/	Art Unit 1638 / Examiner Cynthia Collins
Janet Cotto (Type or printed name)	Confirmation No. 9796

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☒ attorney or agent of record. Registration number 36,434
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 ____

/Dorothy R. Auth/
Signature

Dorothy R. Auth
Type or printed name

(212) 415-8564
Telephone number

March 22, 2007
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 1 forms are submitted.

PRIVACY ACT STATEMENT

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Docket No. 2119-4281US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Wilkinson et al.	**Confirmation No.**	9796
Serial No.:	10/600,230	**Group Art Unit:**	1638
Filed:	June 20, 2003	**Examiner:**	Cynthia Collins

For: Genetic Constructs Having Heterologous 3' Polyadenylation Signal Sequence Motifs That Function In Plants

PRE-APPEAL BRIEF

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Responsive to the Final Official Action dated September 25, 2006, Applicants respectfully request a Pre-Appeal Conference and submit the following remarks for consideration. This Pre-Appeal Brief is being filed along with a Notice of Appeal, the transmittal Requesting a Pre-Appeal Conference and a Petition and Fee for a three-month extension of time.

REMARKS

Claims 1-4, 6, and 9-13 are pending although Claim 6 is withdrawn. Claim 4 has been rejected under 35 U.S.C. § 112, first paragraph as allegedly being noncompliant with the written description requirement. Claims 10-12 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Claims 1-3 and 9-13 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Rothnie H.M. *et al.* Applicants respectfully disagree with these rejections. Applicants urge that these rejections are improper and overlook material of the limitations of the claims. Therefore, proper *prima facie* rejections have not been made.

1. Rejection under 35 U.S.C. §112, first paragraph

Claim 4 has been rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the written description because only one of the 17 successful example sequences tested is at least 90% identical to SEQ ID NO:1. With this rejection, the Examiner overlooked the 16 other sequences that provided the desired results but contained an even lower sequence identity. Applicants amended their claims to the conservative "90%" identity to expedite the examination, only to have the claim rejected for including too few sequences. The instant specification describes a class of sequences from a variety of non-plant sources, including but not limited to, nine *Saccharomyces cerevisiae*, three *Aspergillus nidulans*, one *Pichia pastoris*, and four *Homo sapiens* sequences, that function in the instant invention.

Applicants respectfully disagree that applicants have not described sequences having at least 90% identity when applicants have disclosed sequences in an even broader class of the disclosed genus. Applicants believe that a 90% sequence identity to SEQ ID NO:1 is a reasonable limitation for the disclosed genus to expedite the examination. Although the disclosed sequences are more diverse than 90% to SEQ ID NO:1, each disclosed sequence is a fully functional embodiment of the invention. Moreover, based upon applicant's disclosure, one skilled in the art would know that a wide variety of nucleotide sequences would have the same function provided conserved structural features are maintained. Claim 1 specifies these conserved structural features and Claim 4 depends from Claim 1. Therefore a claim directed to sequences having at least 90% sequence identity to SEQ ID NO:1 is fully supported in light of the specification. For the foregoing reasons, applicants respectfully believe that the Examiner's rejection of Claim 4 constitutes clear error. Applicants respectfully request review and withdraw of this rejection under 35 U.S.C. §112, first paragraph.

2. Rejection under 35 U.S.C. §112, second paragraph

Claims 10-12 have been rejected under 35 U.S.C. §112, second paragraph as allegedly failing to point out and distinctly claim the invention. The Examiner has taken the position that because certain sequences would fall within the claim based on their sequence, a specific comparative sequence is needed to determine the scope of the claim. Applicants

respectfully disagree with this rejection because the Examiner has overlooked the material limitations already in the claims.

The claim language defines two parameters, one is based on the organismal source of the sequence and its ability to function in that organism, and the second is based on sequence identity to known sequences. Each parameter is independent but both must be met for the sequence to fall within the scope of the claims. The Examiner admits that one skilled in the art can readily determine nucleotide sequence termination function but incorrectly maintains that an additional comparative sequence is needed to determine the structure of the claim. In fact, the claims already contain this comparative sequence in the recitation of "at least 70% identity to a native fungal 3' termination sequence" and "at least 90% identity to a native plant 3' termination sequence" (*e.g.* claim 10). These known native fungal or plant 3' termination sequences in light of the claim requirement that the claimed sequence be at least X% identical to it, are the nucleotide sequences the Examiner is requiring. Just as the Examiner suggests, one skilled in the art would use these known sequences to determine whether his sequence falls within the scope of the claims. Therefore, maintaining this rejection under 35 U.S.C. §112, second paragraph is a clear factual error and should be reversed. Review and withdrawal of this rejection is respectfully requested.

3. Rejection under 35 U.S.C. §102(b)

Claims 1-3 and 9-13 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Rothnie *et al,* which discloses the polyadenylation sequence of the cauliflower mosaic virus (CaMV). Applicants respectfully disagree with this rejection because the scope of the inventive is not covered by Rothnie *et al.*

The scope of the invention covers non-plant 3' termination sequences. As discussed in both paragraph 0005 and Rothnie *et al.*, the existing literature indicates that plant cells do not recognize non-plant 3' termination sequences. It was unexpected for the instant inventors to find functionality with various non-plant 3' termination sequences. The inventive composition covers these non-plant 3' termination sequences that were not disclosed in the existing literature, including Rothnie *et al.*

Rather, Rothnie *et al.* describes CaMV polyadenylation sequences. CaMV is cauliflower mosaic virus, that is, this organism is one that lives and propagates itself in plant cells. CaMV elements, including the polyadenylation sequences, are specifically excluded from the express language of the claims by the recitation of the term "non-plant" in the claims. Applicants define this term in the specification in paragraph 40, on page 9 as follows: "the term 'non-plant' refers to any composition that is not identical to a composition found in plants." CaMV is a plant virus; it is a "composition found in plants." As defined above, such compositions are strictly excluded by the use of the term "non-plant."

The Examiner has taken the position that because the CaMV sequences may meet the other limitations of the claims, these sequences fall within the scope of the claims. Applicants respectfully disagree and believe this interpretation overlooks a material limitation of the claim; the recitation "non-plant". "Non plant" is an exclusionary term, *i.e.,* a negative limitation, which eliminates certain components that would otherwise fall within the scope of the claim. Negative limitations are accepted under U.S. Patent Practice (*See* MPEP § 2173.01) and must be considered when determining the scope of a claim containing it. Therefore, the CaMV plant virus sequences fail to meet the limitation of "non-plant" because all CaMV sequences are expressly not covered by the scope of the claims. Applicants respectfully believe that the Examiner overlooked the inventive composition, including the structural limitation in the claims. Applicants urge this constitutes clear error. Review and withdrawal this rejection under 35 U.S.C. §102(b) is respectfully requested.

AUTHORIZATION

The Commissioner is hereby authorized to charge any fees which may be required for consideration of this Pre-Appeal Brief to Deposit Account No. 13-4500, Order No. 2119-4281US1.

The Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **13-4500**, Order No. 2119-4281US1.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: March 22, 2007 By: _____

Dorothy Auth
Registration No. 36,434
(202) 857-7887 Telephone
(202) 857-7929 Facsimile

Correspondence Address:
Morgan & Finnegan, L.L.P.
3 World Financial Center
New York, New York 10281-2101
(212) 415-8700 Telephone
(212) 415-8701 Facsimile